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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,361	12/10/2001	Gyorgy Lajos Kis	OP V-30341B	6955
1095 7	590 03/26/2003			
THOMAS HOXIE NOVARTIS, PATENT AND TRADEMARK DEPARTMENT ONE HEALTH PLAZA 430/2			EXAMINER	
			JOYNES, ROBERT M	
EAST HANOVER, NJ 07936-1080			ART UNIT	PAPER NUMBER
			1615	0
			DATE MAILED: 03/26/2003	Y

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary		Application No.	Applicant(s)			
		10/016,361	KIS ET AL.			
		Examiner	Art Unit			
		Robert M. Joynes	1615			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
A SH THE - Exter after - If the - If NO - Failu - Any I	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication, D (35 U.S.C. § 133).			
1)	Responsive to communication(s) filed on 15 N	November 2002 .				
2a) <u></u> □	This action is FINAL. 2b)⊠ Thi	is action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
-						
	Claim(s) <u>1-14</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.					
	Claim(s) is/are allowed.					
	☑ Claim(s) is/are allowed. ☑ Claim(s) <u>1-14</u> is/are rejected.					
	Claim(s) <u>6 and 12</u> is/are objected to.					
•		r election requirement.				
,	on Papers	•				
9) 🗌 🤈	The specification is objected to by the Examine	r.				
10) 🔲	The drawing(s) filed on is/are: a)☐ accep	eted or b) objected to by the Exam	miner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
* 5	3. Copies of the certified copies of the prior application from the International But See the attached detailed Office action for a list	reau (PCT Rule 17.2(a)).				
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachmen	t(s)	•				
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal I	r (PTO-413) Paper No(s) Patent Application (PTO-152)			
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DETAILED ACTION

Receipt is acknowledged of applicants' Supplemental Information Disclosure Statement filed on October 3, 2002 and their Amendment and Response filed on November 15, 2002.

Claim Objections

Claims 6 and 12 are objected to because of the following informalities: They are identical claims. Appropriate correction is required. It is suggested that Claim 6 be cancelled. No claims depend from Claim 6 whereas some claims do depend from Claim 12.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9 of U.S. Patent No. 6,455,547. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent No. 6,455,547 teaches a composition comprising a salt of ketotifen at a concentration of 0.0345%, glycerol at a concentration of 2.125% and benzalkonium chloride at a concentration of 0.01%. The composition further contains an antioxidant. It would be obvious to one of ordinary skill in the art at the time the invention was made to prepare an ophthalmic solution containing ketotifen, glycerol and benzalkonium chloride in the specific concentrations recited in the instant claims. The addition of the antioxidant does not materially change the composition of the instant claims and is therefore rendered obvious by U.S. Patent No. 6,455,547.

Applicants have filed a Terminal Disclaimer that obviates the previous double patenting rejection over U.S. Patent No. 6,395,756.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurasawa et al. (JP 62 277323). Kurasawa teaches an ophthalmic solution comprising ketotifen fumarate, benzalkonium chloride, glycerol and water (See Abstract and Translation provided in the IDS). Kurasawa does not teach the exact concentrations recited in the instant application.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare an ophthalmic solution comprising ketotifen fumarate, benzalkonium chloride, glycerol and water.

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One of ordinary skill in the art would have been motivated to do this to prepare an eye solution that is similar in composition to a tear to rewet the eyes of the host/patient.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants arguments filed November 15, 2002 have been considered but are not found to be persuasive. Applicants argue that the Kurasawa reference does not teach the exact concentrations of the components of the composition. Further, applicants allege that the reference teaches away from lower concentration that what are taught in the prior art.

Upon review of the Kurasawa reference, the Examiner fails to see where Kurasawa teaches that a lower concentration is ineffective. Kurasawa teaches a concentration for each component. The instant claims recite a different concentration. It is the position of the Examiner that difference is a matter of degree and not of kind. Absent some unexpected results or criticality of the recited concentrations, the instant claims are rendered obvious by the prior art of record.

Conclusion

Due to the new obvious-type double patenting rejection, this action is deemed non-final.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes Patent Examiner Art Unit 1615 March 19, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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